

(e) a representative of the Food and Drug Administration, Department of Health, Education, and Welfare, inspects the plant and determines that adequate control systems have been installed as listed herein, and as considered necessary in the manufacturing of ophthalmic products.

6321. Vitamin B₁₂ injection. (F.D.C. No. 44485. S. No. 27-407 R.)

QUANTITY: 776 individually ctnd. vials at Minneapolis, Minn., in possession of Ulmer Pharmacal Co.

SHIPPED: 1-13-60, from Decatur, Ill.

LABEL IN PART: (Ctn. and vial) "L.F.B. 12-100 10 cc. For Intramuscular Injection Cat. No. 2185 Each cc. contains: Vitamin B₁₂ Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 mcg. * * * Fortified with: * * * Vit. B₁₂ Cryst. 100 mcg. * * * The Ulmer Pharmacal Company, Minneapolis 3, Minnesota."

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 79 percent of the declared amount of vitamin B₁₂.

LIBELED: 6-8-60, Dist. Minn.

CHARGE: 501(c)—while held for sale, the strength of the article fell below that which it purported to possess; and 502(a)—the unqualified label statement "The Ulmer Pharmacal Company, Minneapolis 3, Minnesota" suggested and implied that the Ulmer Pharmacal Co., was the manufacturer of the article which statement was misleading since the Ulmer Pharmacal Co., was not the manufacturer of the article; and the label statement "Each cc, contains * * * Vitamin B₁₂ activity * * * equivalent to * * * Cyanocobalamin 10 mcg." was false and misleading as applied to an article that contained less than the declared amount of vitamin B₁₂.

DISPOSITION: 7-26-60. Default—destruction.

6322. Chorionic gonadotropin injection. (F.D.C. No. 44504. S. No. 8-858 R.)

QUANTITY: 14 pkgs., each containing 1 10-cc. vial of chorionic gonadotropin and 1 10-cc. vial of a diluent at New Hartford, N.Y.

SHIPPED: 4-10-58, from Chicago, Ill.

RESULTS OF INVESTIGATION: Analysis of the article showed that it contained less than 2,500 international units of chorionic gonadotropin potency per vial.

LIBELED: 6-21-60, N. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article fell below that which it was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 2500 I.U." was false and misleading.

DISPOSITION: 9-14-60. Default—destruction.

DRUGS FOR VETERINARY USE

6323. Veterinary drugs. (F.D.C. No. 44204. S. Nos. 49-689 P, 60-413/4 P.)

QUANTITY: 18 1-lb. cans, 5 10-lb. drums, 1 50-lb. drum, and 2 100-lb. drums, of *Vetrodine* and 16 ctns., each containing 50 boluses (12½ grams), and 24 ctns., each containing 50 boluses (8 grams), of *phenothiazine*, at Portland, Oreg.

SHIPPED: Between 6-26-59 and 12-16-59, from El Cerrito, Calif., by Vetrochem.

LABEL IN PART: (Can or drum) "Vetrodine An Iodine Compound for livestock only * * * Each pound contains: Ethylenediamine Dihydriodide 21